K091806

FEB 22 2010

**510(k) Summaries of Safety and Effectiveness**
**FxDEVICES POGO Screw Instrumentation Tray**
**January 11, 2010**

1. Sponsor Name
FxDEVICES
One South Ocean Blvd., Suite 324
Boca Raton, FL 33432

2.

| | |
|---|---|
| Device Name: | POGO Screw Instrumentation Tray |
| Panel: | General Hospital |
| Classification Name: | Sterilization Wrap |
| CFR Number: | Class II (per 21 CFR 880.6850) |
| Product Code: | KCT |

3. Identification of Predicate or Legally Marketed Device
The POGO Screw Instrumentation Tray is substantially equivalent to the PolyVac Tray cleared under K040223.

4. Device Description:
The POGO Screw Instrumentation Tray is a custom autoclavable, compartmentalized, and perforated tray with a locking lid. It is intended to enclose and protect medical device instrumentation, and to facilitate the sterilization process by allowing sterilant penetration and air removal. The tray is categorized as a cassette and requires complete enclosure in a legally marketed, FDA cleared sterilization wrap.

5. Intended Use
The POGO Screw Instrumentation Tray is intended for the protection, organization and delivery to the surgical field of the POGO Screw Instrumentation Set. It is indicated for over-the-counter use.
The trays are not intended to maintain sterility by themselves. They are designed to facilitate the pre-vacuum autoclave sterilization process when used in conjunction with a wrapping material (FDA cleared sterilization wrap). Wrapping materials are designed to allow air removal, steam penetration/evacuation and maintain the sterility of the internal components.

Sterilization Cycle Parameters

| | | |
|---|---|---|
| Method: Steam<br>Cycle: Pre-vacuum<br>Temperature: 132$^0$C<br>Exposure: 4 minutes<br>Drying Time: 30 minutes | or | Method: Steam<br>Cycle: Gravity<br>Temperature: 132$^0$C<br>Exposure: 15 minutes<br>Drying Time: 80 minutes |

6. Comparison of Technological Characteristics

The 510(k) "Substantial equivalence decision making process (detailed) decision tree" (from CDRH 510(k) manual 92-4158) was utilized to make the following determination of substantial equivalence.

Does the new device have the same intended use?

Yes, the new device has the same intended use as the predicate. Both are used to enclose medical devices during steam sterilization.

Does the new device have the same technological characteristics, e.g. design, materials etc.?

Yes, the design and materials are equivalent. The design and materials used in the POGO Screw Instrumentation Tray, a perforated plastic tray manufactured from thermoplastic RADEL with a stainless steel latch and silicone containment brackets, allows free steam passage and is substantially equivalent to the predicate device. All trays have various dimensions such that the proposed trays and the predicate devices are substantially equivalent in size and volume. The sterilization validation of all trays has met the requirements of the same performance standard, ISO 11134. The associated procedures for the use of the devices, i.e. the manufacturer's recommended sterilization cycles are similar.

Are descriptive characteristics precise enough to ensure equivalence?

Yes, labeling, intended use, and device descriptions ensure equivalence. In addition, sterilization validation is available to ensure equivalency of the devices.

7. Performance Testing

Sterilization Validation was conducted to support equivalency

8. Statement of Equivalency

The POGO Screw Instrumentation Tray is substantially equivalent in design, materials, construction and intended use as those of the predicate. Since the POGO Screw Instrumentation Tray is the same in intended use and technological characteristics as the predicate devices, the POGO Screw Instrumentation Tray does not raise any new safety and efficacy concerns when compared to these similar legally marketed devices.

The test results demonstrate that the POGO Screw Instrumentation Tray is substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 22 2010

Mr. Rich Lipschutz
President
Fxdevices
One South Ocean Boulevard
Boca Raton, Florida 33432

Re: K091806
Trade/Device Name: POGO Screw Instrumentation Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: January 12, 2010
Received: January 21, 2010

Dear Mr. Lipschutz

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Susan Runyon

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K091806

Device Name: POGO Screw Instrumentation Tray

Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091806